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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/827,490	04/06/2001	Elizabeth S. Stuart	08952-008001 / UMA 00-19	5744

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EXAMINER

FORD, VANESSA L

ART UNIT

PAPER NUMBER

1645

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13

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/827,490	<b>Applicant(s)</b> STUART ET AL.	
	<b>Examiner</b> Vanessa L. Ford	<b>Art Unit</b> 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 March 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 41, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 7-10, 15, 18 and 19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-10, 15, 18 and 19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
     If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is ~~objected to~~ by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
     a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |                                                                                              |                                                                             |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other:                                          |

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### FINAL ACTION

1. This Office Action is responsive to Applicant's amendment and response filed March 11, 2003. Claim 15 has been amended. Claim 17 has been cancelled. Claims 18-19 have been added.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

### ***Rejections Maintained***

3. The rejection of claim 15 under 35 U.S.C. 102(b) is maintained for the reasons set forth on pages 3-4, paragraph 4 of the previous Office Action.

The rejection was on the grounds Stuart et al teach purified chlamydial glycolipid exoantigen that is free of other components as determined by sodium dodecylsulfate gel electrophoreses and silver staining. The purified chlamydial glycolipid exoantigen of Stuart, et al appears to be the same as the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's exoantigen with the exoantigen of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the exoantigen of the prior art does not possess the same material structural and functional characteristics of the claimed exoantigen). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that claim 15 had been amended to recite a purified preparation of chlamydial glycolipid exoantigen (GLXA) and amended claim 15 clearly indicates that the Applicants claim a preparation of GLXA that is as a whole free of other components as determined by sodium dodecylsulfate polyacrylamide gel electrophoresis (SDS-

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PAGE) and silver staining. Applicant urges that Stuart et al does not teach preparations of GLXA that are free of other components.

Applicant's arguments filed March 11, 2003 have been fully considered but they are not persuasive. The claims are drawn to a purified preparation of chlamydial glycolipid exoantigen, wherein the preparation is free of other components as determined by sodium dodecylsulfate gel electrophoreses and silver staining. Stuart et al teach purified chlamydial glycolipid exoantigen that is free of other components as determined by sodium dodecylsulfate gel electrophoreses and silver staining. The purified chlamydial glycolipid exoantigen as taught by Stuart et al is free of DNA and RNA. Therefore, Stuart et al meet the limitations of the claimed composition. Applicant has provided no shown side-by-side comparison to show that the claimed chlamydial glycolipid exoantigen preparations differ from that of the prior art. It is the Examiner's position that the chlamydial glycolipid exoantigen of Stuart et al are the same as the chlamydial glycolipid exoantigen preparations of the prior art.

4. The rejection of claims 7-9 under 35 U.S.C. 102(b) is maintained for the reasons set forth on pages 4-5, paragraph 5 of the previous Office Action.

The rejection was on the grounds that MacDonald et al teach a covalently bound immune complex comprising paramagnetic particles (i.e. carrier group), GLXA, GLXA-antibody and GLXA-antibody labeled monoclonal GLXA-antibody IgG) (column 14, lines 34-40). The linker used to couple the carrier group to the oligosaccharide would be inherent in the teachings of the prior art. The composition of MacDonald, et al appears to be the same as the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's composition with the composition of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the composition of the prior art does not possess the

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same material structural and functional characteristics of the claimed composition). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that the claims recite compositions that include discrete oligosaccharides(s), not whole GLXA including such as an oligosaccharide(s).

2 Applicant urges that claim 18 has been added to recite a composition comprising a carrier group coupled to an isolated oligosaccharide capable of binding anti-GLXA monoclonal antibody 89MS30. Applicant urges that claim 18 indicates clearly that the recited composition includes a discrete oligosaccharide that is not part of the whole GLXA. Applicant urges that newly added claim 19 recites that the carrier group is selected from bovine serum albumin (BSA), tetanus toxoid, diphtheria CRM197 protein (CRM 197), ovalbumin and an organic polymer. Applicant urges that MacDonald et al do not disclose using any of the materials recited in newly submitted claims 19 as carrier groups.

Applicant's arguments filed March 11, 2003 have been fully considered but they are not persuasive. Claims 7-9 are drawn to a composition comprising a carrier group coupled to an oligosaccharide obtained from a chlamydial glycolipid. MacDonald et al teach a covalently bound immune complex comprising paramagnetic particles (i.e. carrier group), GLXA, GLXA-antibody and GLXA-antibody labeled monoclonal GLXA-antibody IgG) (column 14, lines 34-40). The linker used to couple the carrier group to the oligosaccharide would be inherent in the teachings of the prior art. Therefore, MacDonald et al meet the limitations of the claims 7, 8, and 9.

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Newly submitted claim 18 is drawn to a composition comprising a carrier group coupled to an isolated oligosaccharide capable of binding anti-GLXA monoclonal antibody 89MS30. The claim limitation "...capable of binding anti-GLXA monoclonal antibody 89MS30" would be inherent in the teaching of the prior art. Therefore, MacDonald et al meet the limitations of the claim 18. There is nothing on the record to suggest that claimed composition differs from that of the prior art, since Applicant has provided no side-by-side comparison to show that the claimed composition differs from that of the prior art.

As to claim 19, see the following rejection that includes claim 19.

5. The rejection of claims 7-10 and newly added claims 18 and 19 under 35 U.S.C. 103(a) as being unpatentable over MacDonald et al in view of Smith et al is maintained for the reasons set forth on pages 5-6, paragraph 6 of the previous Office Action.

The rejection was on the grounds that MacDonald et al teach purified chlamydial exoglycolipid antigen (GLXA) (column 8, lines 35-36). MacDonald et al teach a covalently bound immune complex comprising paramagnetic particles (i.e. carrier group), GLXA, GLXA-antibody and GLXA-antibody labeled monoclonal GLXA-antibody IgG) (column 14, lines 34-40).

MacDonald et al do not teach the use of linker 2-(4-aminophenyl)ethylamine linkers.

Smith et al teach the  $\beta$ -(p-aminophenyl)ethylamide (i.e. 2-(4-aminophenyl)ethylamine) can be used to couple proteins via their phenylisothiocyanate intermediates under conditions that preserve labile sugar linkages (see the Abstract). Smith et al teach the coupling of oligosaccharides to bovine serum albumin and keyhole limpet hemocyanin (see the Abstract). Smith et al teach that rabbits immunized with the synthetic glycoproteins produced antibodies directed against the oligosaccharides (see the Abstract).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to use the  $\beta$ -(p-aminophenyl)ethylamide (i.e. 2-(4-

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aminophenyl)ethylamine) linkers as taught by Smith et al to covalently bond the carrier group (i.e. paramagnetic particles) to the oligosaccharide of MacDonald et al because Smith et al have demonstrated that  $\beta$ -(p-aminophenyl)ethylamide linkers can be used to form oligosaccharide-protein conjugates (see the Abstract). One would be motivated use of  $\beta$ -(p-aminophenyl)ethylamine linkers to produce the claimed chlamydial glycolipid-oligosaccharide conjugated of MacDonald because Smith et al teach the  $\beta$ -(p-aminophenyl)ethylamide (i.e. 2-(4-aminophenyl)ethylamine) can be used to couple proteins via their phenylisothiocyanate intermediates under conditions that preserve labile sugar linkages (see the Abstract).

Applicant urges that Smith does not provide the information missing in MacDonald et al. Applicant urges that Smith does not teach chlamydial glycolipids such as GLXA. Applicant urges that Smith does not teach a method to prepare a GLXA component for derivatization such as using trifluoroacetylation.

Applicant's arguments filed March 11, 2003 have been fully considered but they are not persuasive. It is the Examiner's position that applicant argues the references individually without clearly addressing the combination of teachings. It is the combination of all of the cited and relied upon references which make up the state of the art with respect to the claimed invention. The teachings of MacDonald et al have already been disclosed above. The claims are drawn to a composition comprising a carrier group coupled to an oligosaccharide obtained from a chlamydial glycolipid, wherein the glycolipid is chlamydial glycolipid exoantigen, wherein the carrier group is coupled to the oligosaccharide by a linker, wherein the linker is 2-(4-aminophenyl)ethylamine and the composition of claim 7, wherein the carrier group is selected from the group consisting of bovine serum albumin (BSA), tetanus toxoid, diphtheria CRM197 protein (CRM197), ovalbumin and an organic polymer. The Examiner agrees that MacDonald et al teach compositions that comprise a carrier

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group coupled to an oligosaccharide obtained from chlamydial glycolipid wherein the carrier group is coupled to the oligosaccharide by a linker do not specifically teach the use of a 2-(4-aminophenyl)ethylamine linker. However, Smith et al teach the  $\beta$ -(p-aminophenyl)ethylamide (2-(4-aminophenyl)ethylamine) can be used to couple proteins. Smith et al further teach the coupling of oligosaccharides to bovine serum albumin and keyhole limpet hemocyanin (see the Abstract). It would be obvious to use 2-(4-aminophenyl)ethylamine) as a linker to couple an oligosaccharide obtained from chlamydial glycolipid to a carrier group because Smith et al have demonstrated that  $\beta$ -(p-aminophenyl)ethylamide linkers can be used to form oligosaccharide-protein conjugates using bovine serum albumin (BSA) and keyhole limpet hemocyanin as carrier groups (see the Abstract). Applicant is arguing limitations that are not in the claims with their assertion that "Smith does not teach a method to prepare a GLXA component for derivatization by using trifluoroacetylation". It should be remembered that the claims are drawn to a composition which is a product and not a method. There is nothing on the record to show that the combination of teachings would not suggest the claimed invention.



***New Grounds of Rejection Necessitated by Amendment***

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 18 is drawn to a composition comprising a carrier group coupled to an isolated oligosaccharide wherein the oligosaccharide is capable of binding anti-GLXA monoclonal antibody 89MS30.

Because it is not clear that antibody 89MS30 is known and publicly available or can be reproducibly isolated from nature without undue experimentation and because the claims require the use of a suitable deposit for patent purposes a deposit in a public repository is required. Without a publicly available deposit of monoclonal antibody 89MS30, one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed. Exact replication of the cell line is an unpredictable event.

Applicant's referral to the deposit of monoclonal antibody 89MS30 on page 16 of the specification is an insufficient assurance that all required deposits have been made and all the conditions of 37 CFR 1.801-1.809 have been met.

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If the deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by the International Depository Authority under the provisions of the Budapest Treaty and that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application. These requirements are necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State. Amendment of the specification to recite the date of the deposit and the complete name and full street address of the depository is required. If the deposits have not been made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR 1.801-1.809, assurances regarding availability and permanency of deposits are required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

(a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request;

(b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application;

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(c) the deposits will be maintained in the public repository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

(d) the deposits will be replaced if they should become nonviable or non-replicable.

In addition, a deposit of biological material that is capable of self-replication either directly or indirectly must be viable at the time of deposit and during the term of deposit. Viability may be tested by the repository. The test must conclude only that the deposited material is capable of reproduction. A viability statement for each deposit of biological material not made under the Budapest Treaty must be filed in the application and must contain:

- 1) The name and address of the depository;
- 2) The name and address of the depositor;
- 3) The date of deposit;
- 4) The identity of the deposit and the accession number given by the depository;
- 5) The date of the viability test;
- 6) The procedures used to obtain a sample if test is not done by the depository; and
- 7) A statement that the deposit is capable of reproduction.

As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the deposit was made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to

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corroborate that the monoclonal antibody 89MS30 in the specification as filed is the same as that deposited in the depository. Corroboration may take the form of a showing a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed. Applicant's attention is directed to In re Lundack, 773 F.2d.1216, 227 USPQ (CAFC 1985) and 37 CFR 1.801-1.809 for further information concerning deposit practice.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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8. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

- Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 308-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.

  
Vanessa L. Ford  
Biotechnology Patent Examiner  
May 12, 2003

  
**PATRICIA A. DUFFY**  
**PRIMARY EXAMINER**